

REMARKS

1. Preliminary Remarks

Claims 1-62 are currently pending. Claims 1-47 and 56-62 were withdrawn from consideration. Claims 48-55 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Claims 48-52 and 55 were rejected under 35 U.S.C. §103 as obvious over Minoia *et al.* U.S. Patent No. 5,811,451. Claims 48-52 and 55 were also rejected under 35 U.S.C. §103 as obvious over Bernstein U.S. Patent No. 4,466,969. An objection was made to the specification for including embedded hyperlinks.

Applicant has amended claim 48 to include the subject matter of claim 53, which has been cancelled. Applicant makes these amendments solely to expedite prosecution and reserve the right to pursue additional claims, including claims as originally filed, in one or more timely filed continuing applications.

2. The Specification Does Not Have Embedded Hyperlinks

The Office Action objected to the specification because the specification includes website addresses for the commercial databases used as sources of chemical entities. The Office Action stated

The attempt to incorporate subject matter into this application by reference to the many commercial databases such as <http://mdli.com> at page 42 is improper because Applicants have embedded a hyperlink which is impermissible and requires deletion. This attempt to incorporate subject matter into the patent by reference is improper because PTO policy does not permit the PTO to link to any commercial sites since the PTO exercises no control over those organizations, views or accuracy of the information contained on those outside sites. Appropriate correction is required.

(Office Action, page 2 (emphasis added)). Applicant did not intend to embed hyperlinks in the specification, but rather to identify website addresses. Applicant filed the present application in paper form, so no "hyperlinks" were included in the application as filed. Although the website addresses were underlined in the application papers, the underlining was not intended to indicate that the website addresses were hyperlinks.

The website addresses need not be underlined in an issued patent. Indeed, when the USPTO published the present application, it did not include the underlining (U.S. Patent Application Publication No. US 2003/0130171 A1, paragraph 207), indicating that the USPTO did not view the website addresses to be hyperlinks. Since the specification does not include hyperlinks but rather includes website addresses, the objection may be withdrawn.

3. Claims 48-55 Comply With The Written Description Requirement

The Office Action of June 18, 2004 rejected claims 48-55 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Office Action states that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The Office Action stated, "This is a written description requirement."

Claims 48-55 are original claims and have been pending since the filing date of the present application. These original claims are part of the specification and provide their own written description. "It is now well settled that a satisfactory description may be in the claims or any other portion of the originally-filed specification." MPEP 2163, p. 2100-159 (8th Ed., Rev 1 (Feb. 2003) (citations omitted)). The Office Action is incorrect that claims 48-55 contain subject matter which was not described in the specification; original claims 48-55 provide their own verbatim description in the originally-filed specification.

Since original claims can provide their own written description, rejections based on the written description requirement are usually made where the applicant is amending claims or adding new claims. "There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. . . . Consequently, rejection of an original claim for lack of written description should be rare." MPEP 2163, p. 2100-163 (8th Ed., Rev 1 (Feb. 2003) (citations omitted)). This is not a situation where the applicant is amending claims or adding new claims. Original claims 48-55 have been part of the specification since its filing.

The Office Action stated that the specification failed to provide any experiments that show that the claimed composition would be effective for treating any microbial infection in a human or any other animal. The Office Action also stated that the specification at pages 10-11 only discloses predictive compositions and Examples 1-6 fail to teach a composition comprised of a) an opioid inhibitor of an ABC transporter; and b) an anti-microbial agent. Applicant submits that the written description requirement does not require experiments or working examples. In fact, there is no requirement for a working example in any part of 35 U.S.C. §112. As noted in the context of enablement, "An applicant need not have actually reduced the invention to practice prior to filing." MPEP 2164.02, p. 2100-181. Accordingly the specification is not required to disclose experiments or examples of the use of the claimed composition in treating microbial infections.

Nonetheless, in an effort to expedite prosecution, Applicant has amended the preamble of claim 48 to delete the phrase "for the treatment of a microbial infection." The deletion of this phrase from the preamble does not alter the scope of the claim but rather clarifies that claim 48 does not require the step of treating a microbial infection. Claim 48 is drawn to a composition comprising an opioid inhibitor of the ABC drug transporter that is capable of inhibiting a drug transporter protein. The Examples disclose that various opioid inhibitors can be used to inhibit a drug transporter protein. For example, Example 1 shows that naloxone, naltrexone and nalmefene are capable of inhibiting human PGP-mediated transport of digoxin.

Applicant submits that claims 48-55, as originally filed and as amended, fully comply with the written description requirement of 35 U.S.C. §112, and the rejection should be withdrawn.

4. Claims 48-52 and 55 Are Not Obvious In View of Minoia *et al.* or Bernstein

The Office Action rejected claims 48-52 and 55 under 35 U.S.C. §103 as obvious over Minoia *et al.* U.S. Patent No. 5,811,451. Additionally, claims 48-52 and 55 were rejected under 35 U.S.C. §103 as obvious over Bernstein.

Applicant submits that the subject matter of claims 48-55 is not disclosed or suggested by Minoia *et al.* or Bernstein. The Office Action incorrectly concludes that

one of ordinary skill in the art would have modified the teachings of Minoia et al. or Bernstein. There is no motivation or suggestion in the art to modify those references in the manner suggested by the Office Action. Neither Minoia et al. nor Bernstein discloses or suggests a composition comprising a) an opioid inhibitor of an ABC transporter; and b) an anti-microbial agent.

Nonetheless, in an effort to expedite prosecution, Applicant has amended independent claim 48 so that it recites the subject matter of claim 53. Claim 53 was not rejected under 35 U.S.C. §103 as obvious over Minoia et al. or Bernstein. Accordingly, Applicant submits that claim 48 as amended (as well as dependent claims 49-52 and 54-55) are not obvious over Minoia et al. or Bernstein and that the obviousness rejection may properly be withdrawn.

5. Conclusion

For the foregoing reasons, Applicant submits that the amended claims comply with the written description requirement and are not rendered obvious by Minoia et al. or Bernstein. Thus, claims 48-52 and 54-55 are in condition for allowance. The Examiner is invited to telephone Applicant's representative to discuss any questions or if Applicant's representative may be of any assistance to the Examiner in the reconsideration and allowance of this case.

Please charge any fees incurred in connection with this submission to Deposit Account No. 13-0017 in the name of McAndrews, Held & Malloy, Ltd.

Respectfully submitted,



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